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EXAMINER

VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

MAIL DATE	DELIVERY MODE
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09/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/024,258

Applicant(s)

SCHELP ET AL.

Examiner

David J. Venci

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 21, 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 23-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on April 21, 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 04/21/08.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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DETAILED ACTION

Examiner acknowledges Applicants' amendment filed April 21, 2008. Claims 1-31 are pending in this application. Claims 23-31 are direct to non-elected inventions and were withdrawn from consideration in the Office Action dated July 29, 2005. Claims 1-22 are under examination.

Information Disclosure Statement

Examiner acknowledges Applicants' IDS filed April 21, 2008, and thanks Applicants for pointing out that a past Examiner already considered all the IDS documents in a prior Office correspondence.

Applicants' IDS filed April 21, 2008, appears unnecessary because the Office has considered each IDS document at least once. Please ignore the large "X" appearing in Applicants' IDS filed April 21, 2008. This is merely to prevent office personnel from inadvertently listing duplicate citations on the face of issued patents.

Specification

The disclosure is objected to because of the following informalities:

In paragraph [0133], why "sample" is used in the standard assay is not clear.

Clarification is required.

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Claim Rejections - 35 USC § 112 – first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter not described in the specification in such a way as to reasonably convey to skilled persons that the inventors, at the time the application was filed, had possession of the claimed invention.

As amended, independent claims 1 and 19 require, *inter alia*, determining an “L2-dependent” signal assigned to a time domain “T2”. Examiner is unable to locate support for this amendment.

With respect to independent claim 1, the specification either fails to disclose a method step of determining an “L2-dependent” signal (see *e.g.*, specification Examples 11 and 12), fails to disclose a method assigning an “L2-dependent” signal to time domain “T2” (see *e.g.*, specification paragraph [064], Examples 11 and 12), or fails to disclose the claimed “L2-dependent” signal in a one-step method (see 2+ step method, specification paragraph [070]).

With respect to independent claim 19, the specification either fails to disclose a method step of determining an “L2-dependent” signal (see *e.g.*, specification paragraph [056], Examples 11 and 12), fails to disclose a method assigning an “L2-dependent” signal to time domain “T2” (see *e.g.*, specification paragraphs [050], [056], [065], Examples 11 and 12), or fails to disclose the claimed “L2-dependent” signal in a one-step method (see 2+ step methods, specification paragraphs [050], [056], [070]).

Applicants are required to cancel new matter.

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Claim Rejections - 35 USC § 112 – second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the purpose of “binding partner R3, which is associated with a label L2” in the overall method is not clear or appears extraneous. Specifically:

It is not clear whether “binding partner R3, which is associated with a label L2” effectuates Applicants’ illustrated definition of the “hook effect” (see Applicants’ reply, p. 16, second full paragraph, and cited portions of the specification therein), and if so, whether claims 1 and 19 require knowledge or performance of some experimental error.

In claim 19, the purposes of “binding partner R3”, “a member X”, “label L2”, and “member Y” in the overall method are not clear or appears extraneous. Specifically:

It is not clear whether “binding partner R3, which is associated with a label L2” effectuates Applicants’ illustrated definition of the “hook effect” (see Applicants’ reply, p. 16, second full paragraph, and cited portions of the specification therein), and if so, whether claims 1 and 19 require knowledge or performance of some experimental error.

In claims 1 and 19:

How one performs signal “determining” at either “time T1” or “time T2” is not clear. The identity of one or more “time T1” and “time T2” duration or completion functions, inter-method dependencies,

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priorities or simultaneously active processes, if any, or time/clock benchmarks is not clear and appears omitted from the claims and specification.

The phrase “determining[...] an L2-dependent measurement signal[...] using measurement method 2” is indefinite because claims 1 and 19 do not clearly identify specific instance $L1 = L2$ (see specification paragraph [058], measurement method 2 is invoked in specific instance $L1 = L2$).

The phrase “determining[...] an L2-dependent measurement signal or an L1 plus L2-dependent measurement signal using measurement method 2” is indefinite because claims 1 and 19 do not clearly identify a measurement method “L2 plus L1 value” (see specification paragraph [014], measurement method 2 returns L2 only, not the claimed “L1 plus L2”).

In claim 5, step (iii), the simultaneous recitations of “T1 being[...] after adding label L2” and “T2 being after addition of label L2” are indefinite in view of claim 1, step (ii), phrase “time T1 and time T2 are different”. How time T1 and time T2 are “different” in claim 5 is not clear.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 9-12, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Klein *et al.*, 121 J. AM. CHEM. SOC. 5336 (1999).

Klein *et al.* describe a method comprising:

1. incubating a mixture of:
 - a. a sample (see p. 5336, left column, first paragraph, “heterogeneous samples”); and
 - b. three binding partners associating with two labels and a solid phase (see Figure 1, “Binding ligand”, pick three; see *also*, Figure 2, “¹H”) wherein the binding partners have different affinity towards analyte (see Figure 1, “Increasing saturation”);
2. determining analyte label-dependent signals using different methods (See Figure 2, *comparing* Fig. 2(a) versus 2(b)) at different times (See p. 5337, paragraph bridging left and right columns, last sentence).

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Response to Arguments

In prior Office Action, claims 1-10, 16, 17 and 19-22 were rejected under 35 U.S.C. 102(b) as being anticipated by Palomäki, 145 J. IMMUNOL. METHODS 55 (1991).

In response, Applicants argue that Palomäki took only one measurement, whereas the claimed invention requires two measurements.

Applicants' argument is principally considered persuasive. Accordingly, this rejection is withdrawn.

In prior Office Action, claims 1-3, 7, 9-12, 16 and 17 were rejected under 35 U.S.C. 102(b) as being anticipated by Klein *et al.*, 121 J. AM. CHEM. SOC. 5336 (1999).

In response, Applicants argue that Klein *et al.* do not teach binding partners associating with two labels and a solid phase. In addition, Applicants argue that Klein *et al.* do not teach an analyte in a sample which is the object of detection.

Applicants' argument has been carefully considered but is not persuasive. Figure 1 depicts at least one binding partner cartoon associating with a solid phase, and Figure 2 depicts hydrogen labels integrally associating with the binding partners. With respect to Applicants' second argument, Klein *et al.* detect label L1 and label L2, which is all claims 1 and 19 currently recite and require.

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Conclusion

No claims are allowable at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is (571)272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's interim supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Assistant Examiner
Art Unit 1641

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641